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Attorneys for Plaintiff
GILEAD SCIENCES, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GILEAD SCIENCES, INC., Plaintiff, v. MERCK & CO, INC., MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC. Defendants.	Case No. **GILEAD'S COMPLAINT FOR DECLARATORY JUDGMENT** **DEMAND FOR JURY TRIAL**

Plaintiff Gilead Sciences, Inc. ("Gilead" or "Plaintiff"), for its Complaint against Defendants Merck & Company, Inc. ("Merck & Co."), Merck Sharp & Dohme Corporation, and Isis Pharmaceuticals, Inc. ("Isis") to the best of its knowledge, information and belief, and through its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of non-infringement and invalidity of United States Patent Nos. 7,105,499 ("the '499 patent") and 8,481,712 ("the '712 patent") under 28 U.S.C. §§ 2201 and 2202.

PARTIES

2. Gilead Sciences, Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. On information and belief, Merck & Co., Inc. is a company organized under the laws of the State of New Jersey with its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

4. On information and belief, Merck Sharp & Dohme Corp. is a company organized under the laws of the State of New Jersey with its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

5. On information and belief, Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co., Inc. (collectively, "Merck").

6. On information and belief, Isis Pharmaceuticals, Inc. is a company organized under the laws of the State of Delaware with its principal place of business at 2855 Gazelle Court, Carlsbad, CA 92010.

JURISDICTION AND VENUE

7. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338, based on an actual controversy between Gilead, on the one hand, and Defendants, on the

other hand, for claims under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq*. Gilead is seeking relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Merck because Merck is registered with the California Department of State to transact business in California and, upon information and belief, regularly transacts business in California, including in this judicial district.

9. On information and belief, Merck has a place of business at 901 S. California Avenue, Palo Alto, CA 94304-1104.

10. On information and belief, Merck has derived substantial revenue from sales of pharmaceutical products in California, including sales of at least hundreds of millions of dollars in 2012.

11. This Court has personal jurisdiction over Isis because, on information and belief, Isis has its principal place of business in California, is registered with the California Department of State to transact business in California, and regularly transacts business in California, including in this judicial district.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400.

13. On information and belief, Merck and Isis are each subject to personal jurisdiction in this judicial district, and thus reside in this judicial district under 28 U.S.C. § 1391(b)(1).

14. A substantial part of the events giving rise to this action have occurred in this judicial district under 28 U.S.C. § 1391(b)(2) because, *inter alia*, Gilead has made the drug at issue in this action, sofosbuvir, in this judicial district; has prepared the New Drug Application for sofosbuvir in this district; has conducted clinical trials in this judicial district; maintains documents in this district; has employees involved in the development of sofosbuvir who reside in this district; and has plans to advertise, market, offer to sell, and sell sofosbuvir from its corporate headquarters in this judicial district upon FDA approval.

15. In addition, and as detailed below, Merck contacted Gilead about the matters alleged herein in this judicial district, including two unsolicited telephone calls to a Gilead

employee in Foster City, CA requesting that Gilead take a license to the '499 and '712 patents, and Merck's letter to the same Gilead employee in Foster City, CA requesting the same, and proposing licensing terms, and a deadline to respond.

THE PATENTS-IN-SUIT

16. On September 12, 2006, the '499 patent, entitled "Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase," issued to Steven S. Carroll, David B. Olsen, Malcolm MacCoss, Balkrishen Bhat, Phillip Dan Cook, Anne B. Eldrup, and Thazha P. Prakash. A copy of the '499 patent is attached to this Complaint as Exhibit A.

17. Merck & Co., Inc. and Isis Pharmaceuticals, Inc. are listed as assignees on the face of the '499 patent.

18. On information and belief, Merck & Co., Inc. has assigned its interest in the '499 patent to Merck Sharp & Dohme Corp.

19. On information and belief, Merck and Isis are co-owners of the '499 patent.

20. On July 9, 2013, the '712 patent, entitled "Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase," issued to Balkrishen Bhat, Anne B. Eldrup, Thazha P. Prakash, Phillip Dan Cook, Robert L. LaFemina, Amy L. Simcoe, Carrie A. Rutkowski, and Mario A. Valenciano. A copy of the '712 patent is attached to this Complaint as Exhibit B.

21. Merck Sharp & Dohme Corp. and Isis Pharmaceuticals, Inc. are listed as assignees on the face of the '712 patent.

22. On information and belief, Merck and Isis are co-owners of the '712 patent.

GILEAD'S PENDING NEW DRUG APPLICATION FOR SOFOSBUVIR, A REVOLUTIONARY NEW THERAPY FOR HEPATITIS C

23. Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines for life-threatening diseases in areas of unmet medical need, including treatment for HIV/AIDS, hepatitis, serious respiratory and cardiovascular conditions, cancer, and inflammation.

24. Hepatitis C virus ("HCV") is a group of related viruses classified into at least six distinct HCV genotypes (genotypes 1-6) that are spread by contact with HCV-infected blood and infect the liver. The prevalence of HCV infection in the U.S. has been estimated between 3.2 and 5.2 million people. Since 2007, there are more deaths in the U.S. due to HCV than HIV. HCV infection is the cause of half of all liver cancer deaths in the U.S. and the most common indication for liver transplants. For every 100 people infected with HCV, 75-85 will develop chronic infection and 60-70 will suffer from HCV-related complications including chronic liver disease, cirrhosis, and death.

25. Most HCV-infected individuals carry the virus for life and thereby remain contagious and able to transmit the virus to others. This is true irrespective of whether an individual's HCV infection progresses to chronic form.

26. Traditionally, chronic HCV infection has been treated with a combination of antiviral medicines—ribavirin, interferons, and, more recently, protease inhibitors. In addition to relatively limited efficacy, these available treatments have frequent and, at times, permanent side effects including flu-like symptoms, serious hemolytic anemia, worsening of cardiac disease, weight loss, skin rashes, hair loss, muscle or bone pain, diarrhea, and vomiting. Moreover, these treatments must be taken for prolonged periods—24 to 48 weeks—thereby exacerbating the physical and emotional toll on the infected individuals and their families, which can lead to patient discontinuation of treatment. While liver transplantation can be life-saving for HCV-infected individuals in end-stage liver disease, transplantation presents significant risks and is not a readily available option for patients due to donor shortages and potential organ rejection. Even when available, transplantation is costly and requires ongoing post-procedure care, and for HCV-positive transplant recipients, reinfection is almost universal.

27. Gilead has developed a new, orally administered prescription drug for treatment of chronic HCV infection called sofosbuvir that shortens HCV therapy to no more than 12 to 16 weeks. Invented by Pharmasset, sofosbuvir is a nucleotide analogue NS5B polymerase inhibitor

for the treatment of chronic HCV infection. Ultimately, it combats the disease by suppressing the replication of viral RNA and directly interfering with the HCV life cycle.

28. Sofosbuvir is an all-oral treatment that sets a new standard of care for treating chronic HCV infection. Because of this, sofosbuvir will form the basis for a revolution in hepatitis C treatment.

29. On November 21, 2011 Gilead and Pharmasset announced that the companies had signed a definitive agreement under which Gilead would acquire Pharmasset. On January 17, 2012 Gilead announced that its acquisition of Pharmasset had been completed.

30. On April 8, 2013, Gilead filed a new drug application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval of sofosbuvir as a once-daily oral therapy for chronic HCV infection. The data submitted in this NDA support the use of sofosbuvir and ribavirin as an oral therapy for patients with genotype 2 and 3 HCV infection, and for sofosbuvir in combination with ribavirin and pegylated interferon for treatment-naïve patients with genotype 1, 4, 5 and 6 HCV infection (hereinafter "Sofosbuvir NDA").

31. On June 7, 2013, Gilead issued a press release publicly announcing that FDA had granted priority review of Gilead's Sofosbuvir NDA. FDA grants priority review status to drug candidates that may offer major advances in treatment over existing options. FDA has set a target review date of December 8, 2013 for the Sofosbuvir NDA.

32. Gilead has made substantial preparation to make, sell, and offer to sell sofosbuvir in the United States, including manufacturing sufficient quantities for sale upon FDA approval.

THE PRESENCE OF A CASE OR CONTROVERSY

Merck's Stake in the HCV Market

33. Merck is a worldwide pharmaceutical company that offers therapeutic products related to, among other things, infectious diseases, including HCV infection.

34. In 2011, FDA approved Merck's NDA for the prescription drug boceprevir, which is a protease inhibitor used to treat long-lasting HCV infection and is marketed under the trade

name Victrelis®. On information and belief, Merck's Victrelis® sales currently exceed $500 million annually.

35. On information and belief, Merck monitors the drug-development pipelines, clinical trials, and acquisitions of competitor pharmaceutical companies, including activities related to potential therapeutic products for the treatment of HCV infection. On information and belief, Merck has monitored and continues to monitor such activities as related to Gilead.

36. On information and belief, Merck became aware in November 2011 that Gilead entered into a deal to acquire Pharmasset Inc. On information and belief, Merck was aware at least as of that time that Pharmasset Inc. had been developing an experimental HCV drug referred to as PSI-7977, which is now known as sofosbuvir. On information and belief, Merck was also aware at that time that some analysts predicted that PSI-7977 could generate billions of dollars in revenue annually over the long term.

37. On information and belief, Merck was aware by the end of 2011 that PSI-7977, in combination with ribavirin and pegylated interferon, was publicly reported to have cured 100% of people with HCV genotypes 2 and 3 in Phase IIb clinical trials.

38. On information and belief, Merck has monitored and continues to monitor the outcome of clinical trials of PSI-7977.

39. On information and belief, Merck became aware of Gilead's filing of the Sofosbuvir NDA in April 2013.

40. On information and belief, Merck became aware of FDA's granting of priority review status of the Sofosbuvir NDA in June 2013.

41. On information and belief, Merck has monitored since April 2013 and continues to monitor today the FDA approval status of the Sofosbuvir NDA.

42. If approved, the Sofosbuvir NDA drug product will directly compete against Merck's Victrelis® product in the HCV market.

Merck's Intent to Enforce its Patents Against Sofosbuvir

43. On information and belief, Merck has demonstrated a willingness to protect the market position of its proprietary drugs through patent infringement litigation. On information and belief, Merck has brought more than 25 patent infringement suits in the past 4 years alone in the United States to protect its proprietary drugs' market share.

44. In support of these patent enforcement activities, Merck applies for and prosecutes patent applications in the therapeutic areas in which it does business. These include filing patents for drug compounds useful for treating HCV infection and methods of treating HCV infection.

45. On information and belief, during prosecution of the '499 patent, Merck became aware of competitive patent activities by Pharmasset in the areas of compounds useful for treating HCV infection and/or methods of treating HCV infection.

46. On information and belief, during prosecution of the '499 patent, Merck amended its pending claims in an attempt to cover compounds useful for treating HCV infection and/or methods of treating HCV infection that were the subject of pending Pharmasset patent applications so as to obtain patent rights to attempt to exclude Pharmasset from the market or extract royalty payments in relation to potential future Pharmasset products.

47. On information and belief, during prosecution of the '712 patent, Merck became aware of compounds in Pharmasset's pipeline, including PSI-7977, that were experimental treatments for HCV infection.

48. On information and belief, during prosecution of the '712 patent, Merck amended its pending claims in an attempt to cover compounds related to PSI-7977 so as to obtain patent rights to attempt to exclude from the market or extract royalty payments for sofosbuvir.

Merck's Assertion of Its Patents

49. On July 29, 2013, less than three weeks after the '712 patent issued, Merck's Executive Director of Corporate Licensing, Ms. Pamela Demain, made an unsolicited telephone call to Gilead's Senior Director of Corporate Development, Ms. Liz Bhatt. Ms. Bhatt works, and received the call, at Gilead's offices in Foster City, California. Ms. Demain did not reach Ms.

Bhatt, and left a message asking for a return call. On July 29 or July 30, Ms. Bhatt called Ms. Demain back. Ms. Demain indicated that she was not prepared to talk.

50. On Friday, August 2, 2013, Ms. Demain placed a second call to Ms. Bhatt. Ms. Demain did not reach Ms. Bhatt, and left a message asking for a return call.

51. On Monday, August 5, 2013, Ms. Demain placed a third call to Ms. Bhatt. On that call, Ms. Demain requested that Gilead take a license to the '499 and '712 patents in relation to Gilead's sofosbuvir and informed Ms. Bhatt of Merck's terms.

52. Also on August 5, 2013, Ms. Demain sent Ms. Bhatt at her Foster City office a letter by e-mail following up on their August 5, 2013 telephone call. In that letter, Merck stated its desire that Gilead take a non-exclusive sublicensable license to Merck's '499 and '712 patents and related foreign counterparts for commercialization of sofosbuvir. A copy of the August 5, 2013 letter is attached to this Complaint as Exhibit C.

53. The August 5, 2013 letter further provided the following license terms:

> In consideration of the rights to be granted, Gilead shall pay to Merck a 10% royalty on the Net Sales of Licensed Product (as defined in the Agreement) by Gilead, its distributors or sublicensees, including sales of Licensed Product that is co-packaged with one or more other pharmaceutical products, from the first sale of sofosbuvir until the expiration of the last to expire patent within the Licensed Patent Rights.

54. The August 5, 2013 letter requested a reply by August 31, 2013 and further stated that Merck already has one licensee on the terms specified in the letter.

55. A 10% royalty on products containing sofosbuvir is a prohibitive demand. On information and belief, Merck understands that its license demand is prohibitive and instead is meant to threaten Gilead, on the eve of approval of sofosbuvir, with the prospect of an infringement suit and a substantial claim for damages.

56. Merck's imposition on Gilead of the August 31, 2013 deadline to respond to its August 5, 2013 letter demonstrates a course of conduct consistent with Merck's willingness to enforce its patent rights.

57. On information and belief, Merck's communications to Gilead regarding the '499 and '712 patents demonstrates Merck's belief that Gilead has been or will be engaging in infringing activity following FDA's approval of the Sofosbuvir NDA.

58. Gilead has the right to manufacture, use, offer to sell, sell, and/or import the drug product that is the subject of the Sofosbuvir NDA without a license to the '499 and '712 patents.

59. The facts alleged herein show that a substantial controversy exists between Gilead and Merck, parties having adverse legal interests, regarding the validity and alleged infringement of the '499 and '712 patents, and that this controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

60. On information and belief, if this action is dismissed for lack of subject matter jurisdiction, Merck will sue Gilead for infringement of the '499 and '712 patents in this or another court promptly upon commencement of the commercial sale of sofosbuvir.

61. The Court may and should exercise its broad discretion to adjudicate this action under the Declaratory Judgment Act. There is no better or more effective remedy or forum for resolving the present controversies between the parties regarding sofosbuvir. Such adjudication will serve the underlying purpose of the Declaratory Judgment Act by resolving legal disputes between Gilead and Merck regarding Gilead's legal right to manufacture, sell, offer to sell, and import sofosbuvir. It will also serve the public interest by settling the adverse legal rights between Gilead and Merck as it relates to the availability of a promising new treatment for HCV infection. These disputes should be resolved efficiently and economically in this action, deciding the controversies between the parties with certainty, completeness, and finality.

COUNT I

(Declaratory Judgment of Non-infringement of the '499 Patent)

62. Paragraphs 1 to 61 are incorporated herein as set forth above.

63. An actual and justiciable case or controversy exists between Gilead and Merck regarding the alleged infringement of the '499 patent by the drug product that is the subject of the Sofosbuvir NDA.

64. The manufacture, use, offer for sale, sale, and/or importation of sofosbuvir and the drug product that is the subject of the Sofosbuvir NDA has not infringed, does not infringe, and would not, if marketed, directly or indirectly infringe any valid claim of the '499 patent, either literally or under the doctrine of equivalents.

65. Gilead is entitled to a judgment declaring that the manufacture, use, offer for sale, sale and/or importation of sofosbuvir and the drug product that is the subject of the Sofosbuvir NDA before expiration of the '499 patent does not and will not constitute infringement of the '499 patent.

COUNT II

(Declaratory Judgment of Invalidity of the '499 Patent)

66. Paragraphs 1 to 65 are incorporated herein as set forth above.

67. An actual and justiciable case or controversy exists between Gilead and Merck regarding the invalidity of the '499 patent.

68. The claims of the '499 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

69. Gilead is entitled to judgment declaring that the claims of the '499 patent are invalid.

COUNT III

(Declaratory Judgment of Non-infringement of the '712 Patent)

70. Paragraphs 1 to 69 are incorporated herein as set forth above.

71. An actual and justiciable case or controversy exists between Gilead and Merck regarding the alleged infringement of the '712 patent by the drug product that is the subject of the Sofosbuvir NDA.

72. The manufacture, use, offer for sale, sale, and/or importation of sofosbuvir and the drug product that is the subject of the Sofosbuvir NDA has not infringed, does not infringe, and

would not, if marketed, directly or indirectly infringe any valid claim of the '712 patent, either literally or under the doctrine of equivalents.

73. Gilead is entitled to a judgment declaring that the manufacture, use, offer for sale, sale and/or importation of sofosbuvir and the drug product that is the subject of the Sofosbuvir NDA before expiration of the '712 patent does not and will not constitute infringement of the '712 patent.

COUNT IV

(Declaratory Judgment of Invalidity of the '712 Patent)

74. Paragraphs 1 to 73 are incorporated herein as set forth above.

75. An actual and justiciable case or controversy exists between Gilead and Merck regarding the invalidity of the '712 patent.

76. The claims of the '712 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

77. Gilead is entitled to judgment declaring that the claims of the '712 patent are invalid.

RELIEF SOUGHT

WHEREFORE, Plaintiff respectfully requests that this Court enter the following relief pursuant to 28 U.S.C. §§ 2201 and 2202:

a. That a declaration be issued under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, sale, and/or importation of sofosbuvir and the drug product that is the subject of the Sofosbuvir NDA before expiration of the '499 patent does not and will not infringe any valid claim of the '499 patent;

b. That a declaration be issued under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, sale, and/or importation of sofosbuvir and the drug product that is the subject of the Sofosbuvir NDA before expiration of the '712 patent does not and will not infringe any valid claim of the '712 patent;

c. That a declaration be issued under 28 U.S.C. § 2201 that the claims of the '499 patent are invalid;

d. That a declaration be issued under 28 U.S.C. § 2201 that the claims of the '712 patent are invalid;

e. That an injunction be issued enjoining Defendants and their agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Gilead or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Gilead, or charging them either orally in writing with infringement of the '499 or '712 patents;

f. That this case be adjudged an exceptional case under 35 U.S.C. § 285, and awarding Plaintiff its attorneys' fees and costs;

g. That the Court award all other and further relief as it deems just and proper.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby requests a trial by jury of all issues so triable.

Dated: August 30, 2013

FISH & RICHARDSON P.C.

By: */s/ John M. Farrell*
John M. Farrell

Attorneys for Plaintiff
GILEAD SCIENCES, INC.